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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,381	09/25/2001	Gary Lynch	1819.0040001/MAC/LBB	7154

26111 7590 08/18/2003

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EXAMINER
CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
1632	12

DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/961,381	LYNCH ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-78 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 7, 8, 13-15, 17-19, 63, 64, 69-71, 73 and 74, drawn to a method for determining the effect of a substance on the characteristics of a neurodegenerative disease using brain cells and/or brain slices, classified in class 435, subclass 29.

II. Claim 9-12 and 65-68, drawn to a method for determining the effect of a substance on the characteristics of a neurodegenerative disease using a transgenic animal, classified in class 800, subclass 3.

III. Claims 20-35 and 38-54, drawn to a method of obtaining brain cells having characteristics of neurodegenerative disease comprising culturing brain cells in a condition that modulates integrins or integrin receptors and brain cells, classified in class 435, subclass 383.

IV. Claims 55-58 and 76-78, drawn to a method for alleviating the symptoms of a disease state comprising administering an effective amount of an NMDA receptor antagonist, a pharmaceutical composition comprising a compound capable of inhibiting the activity of an NMDA receptor and method for inhibiting the intracellular accumulation of amyloid comprising administering a glutamate receptor antagonist, classified in class 514, subclass 1.

Claims 1-6, 16, 36, 37, 59-62, 72 and 75 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-6, 16, 36, 37, 59-62, 72 and 75. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable

linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I and II are mutually exclusive and independent. While both are to methods of determining the effect of a substance on characteristics of a neurodegenerative disease, invention I is to the method in vitro, that is using brain cells or brain slices and invention II is the method in vivo, that is using a transgenic animal model. Protocols for the in vitro assay and in vivo assay are materially different and separate from each other. Further, neither assay is required for the other assay.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the brain cells of invention III can be used to observe the cellular damage that results from neurodegenerative disease.

Inventions I and IV are independent inventions because they are of a different mode of operation. Invention I is to a method of for determining the effect of a substance on the characteristics of a neurodegenerative that requires in vitro cell culture. Invention IV is to a method of treatment that requires the administration of glutamate receptor agonists. In vitro and in vivo methodologies require materially different and separate protocols. Further, neither invention is need for the implementation of the other method.

Inventions II and III are mutually exclusive and independent methods. Invention II is to an in vivo assay to determine the effects of a compound on the characteristics of a neurodegenerative disease. Invention III to methods of producing a culture of brain cells having characteristics of a neurodegenerative disease. Invention II is to an in vivo assay. Invention III is to a method of in vitro culture. The in vivo assay of invention II is not required for the method of in vitro culture of Invention III, and vice versa.

Inventions II and IV are mutually exclusive and independent methods. Invention II is to an in vivo assay to determine the effects of a compound on the characteristics of a neurodegenerative disease. Invention IV is to methods of treatment comprising administering glutamate receptor antagonists. Each method requires materially different and separate protocols; indicating that invention II and IV are of separate operation.

Inventions III and IV are mutually exclusive and independent. Invention III to methods of producing a culture of brain cells having characteristics of a neurodegenerative disease. Invention IV is to methods of treatment comprising administering glutamate receptor antagonists. Each method requires materially different and separate protocols; indicating that invention III and IV are of separate operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

dc
August 15, 2003